Eight Steps to Create a Winning Clinical Research Study Budget

Part 2 - Identify All the Study Related Tasks to be Performed

By John P. Neal

About the Author

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In Part 1 of this series I addressed how to determine the fully loaded hourly cost of each staff member and the importance of creating a well thought out, defensible study budget. It can be a daunting task, particularly for non-accountants. I have found that many people at clinical research sites who work on study budgets, as well as those who negotiate the Clinical Trial Agreements (CTAs), don't have a background in accounting and are uncomfortable performing the budgeting function. I have observed many site staff struggle with how to tackle this challenge. Fortunately for them, I have a solution!

I have created a simple, eight step approach to developing a clinical research study budget modeled after the process I have successfully followed for years that has resulted in an average increase in budgets of over 53%, with many in excess of 70% higher than what was originally offered by the Sponsor. Following my eight step process will make your task of creating study budgets easier and give you the confidence to negotiate better budgets.

The Eight Steps

The process is broken down into the following distinct steps:

- ***Step 1*** - Determine the fully loaded, productivity adjusted cost of each staff member *(this was the subject of Part 1 of this series)*.
- ***Step 2*** - Identify all the study related tasks that must be performed per the protocol.
- ***Step 3*** - Identify all the non-staff costs of conducting the study visits.
- ***Step 4*** - Determine the time and cost of all the tasks necessary to start-up the study.
- ***Step 5*** - Determine the time and cost for each study visit.
- ***Step 6*** - Summarize all visits and add the totals for each visit.
- ***Step 7*** - Determine the appropriate overhead rate to use.
- ***Step 8*** - Summarize all the costs and expected revenue and determine whether the study, as budgeted, will be profitable.

In this article I will address Step 2. In each subsequent article I will cover the next step until we have covered them all.

Determining the Study Tasks to be Performed

The ***second step*** is to identify the various study related tasks that must be performed per the protocol and to comply with good clinical practice (GCP). Starting with the Schedule of Procedures (sometimes referred to as the Study Flow Sheet) found in the study protocol, create a list of all the tasks that must be performed in order to conduct the study.

Figure 1 below shows an example Schedule of Procedures.

Figure 1

Example Simple Study
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Example Schedule of Procedures (or Study Flow Sheet)

Study Task	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10
INFORMED CONSENT	X									
INCLUSION/EXCLUSION	X	X								
MEDICAL HISTORY	X		X							
RANDOMIZATION			X							
VITAL SIGNS	X	X	X	X	X	X	X	X	X	X
COMPLETE PHYSICAL EXAM		X							X	
BRIEF PHYSICAL EXAM	X		X				X			X
EDEMA ASSESSMENTS	X	X	X	X	X	X	X	X	X	X
ECG - 12 LEAD		X							X	
LAB DRAW & PROCESSING	X	X	X	X	X	X	X	X	X	X
URINALYSIS	X								X	
ADVERSE EVENTS			X	X	X	X	X	X	X	X
CONCOMITANT MEDS	X	X	X	X	X	X	X	X	X	X
DRUG DISTRIBUTION AND ACCOUNTABILITY		X	X	X	X	X	X	X	X	

Although a logical place to start, the Schedule of Procedures is only the starting point. Many of the finer details of the study are excluded from the schedule in favor of brevity. It is best to consider it a "10,000 foot view" of the study procedures, understanding that the closer you get to ground zero, more details will become clear. To create a complete list of tasks to be performed, you must read the entire protocol, considering each element relative to any tasks that must be completed.

I want to stress the importance of having representatives from every department of your site review the protocol in detail and to contribute to your list of tasks that must be performed (and other costs that will be incurred) in order to successfully conduct the study.

Everyone approaches their work with a different educational and experiential filter. A Clinical Research Coordinator may note details specific to the tasks they will have to perform. An accountant may note direct and indirect costs that might not be obvious. The Principal Investigator may note that additional time and care may be required due to the acuity of the subject. Absent the input from all facets of your organization, it is impossible to assemble a complete schedule of tasks and costs.

On the following page, Figure 2 is an example of a budget template that might be provided by the sponsor for the Simple Study in our example.

Figure 2

Example Study Budget Template From Sponsor

Study Task	RATE	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	TOTAL
INFORMED CONSENT	$100	$100										$100
INCLUSION/EXCLUSION	$75	$75	$75									$150
MEDICAL HISTORY	$75	$75		$75								$150
RANDOMIZATION	$100			$100								$100
VITAL SIGNS	$25	$25	$25	$25	$25	$25	$25	$25	$25	$25	$25	$250
COMPLETE PHYSICAL EXAM	$125		$125							$125		$250
BRIEF PHYSICAL EXAM	$75			$75				$75			$75	$225
WOUND SITE ASSESSMENTS	$30	$30	$30	$30	$30	$30	$30	$30	$30	$30	$30	$300
ECG - 12 LEAD	$20		$20							$20		$40
LAB DRAW & PROCESSING	$30	$30	$30	$30	$30	$30	$30	$30	$30	$30	$30	$300
URINALYSIS	$20	$20								$20		$40
ADVERSE EVENTS	$40			$40	$40	$40	$40	$40	$40	$40	$40	$320
CONCOMITANT MEDS	$30	$30	$30	$30	$30	$30	$30	$30	$30	$30	$30	$300
DRUG DISTRIBUTION AND ACCOUNTABILITY	$20		$20	$20	$20	$20	$20	$20	$20	$20		$160
COORDINATOR FEE	$75	$75	$75	$75	$75	$75	$75	$75	$75	$75	$75	$750
INVESTIGATOR FEE	$100	$100	$100	$100	$100	$100	$100	$100	$100	$100	$100	$1,000
SUBJECT STIPEND	$50	$50	$50	$50	$50	$50	$50	$50	$50	$50	$50	$500
SUBTOTAL		$610	$580	$650	$400	$400	$400	$475	$400	$565	$455	$4,935
OVERHEAD	20%	$122	$116	$130	$80	$80	$80	$95	$80	$113	$91	$987
TOTAL COST PER VISIT		$732	$696	$780	$480	$480	$480	$570	$480	$678	$546	$5,922

Figure 3 below is a simple example of changes you might make to the sponsors template based on a review of the protocol.

Figure 3

Example Completed Study Budget with Additions

Study Task	RATE	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	TOTAL
INFORMED CONSENT	$150	$150										$150
INCLUSION/EXCLUSION	$100	$100	$100									$200
MEDICAL HISTORY	$125	$125		$125								$250
RANDOMIZATION	$110			$110								$110
VITAL SIGNS	$25	$25	$25	$25	$25	$25	$25	$25	$25	$25	$25	$250
COMPLETE PHYSICAL EXAM	$175		$175							$175		$350
BRIEF PHYSICAL EXAM	$100			$100				$100			$100	$300
WOUND SITE ASSESSMENTS	$75	$75	$75	$75	$75	$75	$75	$75	$75	$75	$75	$750
ECG - 12 LEAD	$25		$25									$25
LAB DRAW & PROCESSING	$40	$40	$40	$40	$40	$40	$40	$40	$40	$40	$40	$400
URINALYSIS	$25	$25										$25
BLOOD CULTURE	$20	$20	$20	$20	$20	$20	$20	$20	$20	$20	$20	$200
SERUM CHEMISTRY PANEL	$15	$15										$15
SERUM PREGNANCY TEST	$11	$11										$11
ADVERSE EVENTS	$50			$50	$50	$50	$50	$50	$50	$50	$50	$400
CONCOMITANT MEDS	$40	$40	$40	$40	$40	$40	$40	$40	$40	$40	$40	$400
DRUG DISTRIBUTION AND ACCOUNTABILITY	$25		$25	$25	$25	$25	$25	$25	$25	$25		$200
COORDINATOR FEE		$175	$125	$125	$125	$125	$125	$125	$125	$125	$125	$1,300
INVESTIGATOR FEE	$100	$175	$150	$150	$100	$100	$100	$100	$100	$100	$100	$1,175
QUALITY ASSURANCE FEE	$40	$40	$40	$40	$40	$40	$40	$40	$40	$40	$40	$400
SUBJECT STIPEND	$50	$50	$50	$50	$50	$50	$50	$50	$50	$50	$50	$500
SUBTOTAL		$1,066	$890	$975	$590	$590	$590	$690	$590	$765	$665	$7,411
OVERHEAD	31%	$330	$276	$302	$183	$183	$183	$214	$183	$237	$206	$2,297
TOTAL COST PER VISIT		$1,396	$1,166	$1,277	$773	$773	$773	$904	$773	$1,002	$871	$9,708

Note the changes in burgundy. Although this represents only a very simple set of additional items, many more are frequently discovered.

To illustrate further, consider an example from one study I saw recently. The Schedule of Procedures included in the synopsis of the protocol indicated that an eye exam was required, a task that was routinely performed in the Investigators office. Upon review of the full protocol, it became clear that this was not a simple eye exam. The protocol required a thorough exam by an ophthalmologist. For this particular site, this would require engaging the services of a local ophthalmologist during the course of Visit 1 and Visit 8, not only interrupting the flow of the visit, but causing the site to incur additional costs for the services of the ophthalmologist.

Such an oversight can be very costly, particularly when the task is repeated at multiple visits.

Once you have created a detailed list of procedures for one study you can use that list as a starting point for future studies to alert you and your team to tasks that might otherwise be overlooked.

In Part 5 of this series I will explain how to determine the amount of time required to perform each task required to properly conduct the study.

In my next article I will explain ***Step 3*, determining non-staff related direct costs** that account for a significant component of every budget. Although some non-staff direct costs are obvious, others are hidden and easily overlooked. I will explain how to identify and determine the full cost for these items.

As we work through all ***Eight Steps***, you will find that completing a budget analysis will become easy. Armed with a defensible budget, you can negotiate the budget with the sponsor or CRO's with confidence. The negotiation itself is the topic of a future article that will include negotiating the budget as well as the Clinical Trial Agreement (CTA).

Armed with a solid budget analysis and an understanding of what is customary and possible, you will get better budgets as well as better contract terms. And by adding value to your site's studies your value will also increase. That's what I call a "Win, Win" situation!

This is Part 2 of an eight part series that is available at www.premiercmo.com or www.raninstitute.com.
